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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,919	04/16/2004	Alexander Deiters	54-000250US	1323

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER	
GEBREYESUS, KAGNEW H	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,919	DEITERS ET AL.	
	Examiner	Art Unit	
	Kagnew H. Gebreyesus	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 14,18-20, 23-25, 60 and 61drawn to a composition comprising a protein wherein the protein comprises at least one unnatural amino acid and at least one post-translational modification, wherein the at least one post-translational modification comprises attachment of a molecule comprising a second reactive group by a (3+2) cycloaddition to the at least one unnatural amino acid comprising a first reactive group, classified in class 530, subclass 350.

II. Claims 9-13 are drawn to a composition comprising an unnatural amino acid having the chemical structure found in figure 9 classified in class 560 subclass 19.

III. Claim 15 is drawn to a cell comprising an unnatural amino acid classified in class 435, subclass 252.

IV. Claims 16 and 17 are drawn to a composition comprising an azido dye classified in class 443 subclass 440.

V. Claims 21 and 22 are drawn to a composition comprising an alkynyl polyethylene glycol classified in class 534 subclass 640.

VI. Claims 26 and 27 are drawn to a method for synthesizing a p- (proparglyoxy) phenylalanine compound, the method classified in class 435, subclass 106.

VII. Claims 28-30 are drawn to a method for synthesizing an azido dye, the method comprising: providing a dye compound comprising a sulfonyl halide moiety classified in class 548, subclass 443.

VIII. Claims 31-35 are drawn to a method for synthesizing an azido dye, the method comprising: providing an amine-containing dye compound classified in class 548, subclass 443.

IX. Claims 36-39 are drawn to a method for synthesizing a propargyl amide polyethylene glycol, the method comprising: reacting propargylamine with polyethylene glycol (PEG)-hydroxysuccinimide ester in an organic solvent at room temperature classified in class 530, subclass 421.

X. Claims 40 and 41 are drawn to a eukaryotic cell comprising an orthogonal aminoacyl-tRNA synthetase (O-RS), wherein the O-RS preferentially aminoacylates an orthogonal RNA (O-tRNA) with at least one unnatural amino acid in the eukaryotic cell classified in class 435, subclass 252.3.

XI. Claims 42, 43 and 45 are drawn to a polypeptide selected from the group consisting of a polypeptide that comprises an amino acid sequence as shown in any one of SEQ ID NO.: 48-63 classified in class 435, subclass 183.

XII. Claims 44 and 46 are drawn to an antibody or anti-sera specifically immuno-reactive with the polypeptide selected from the group consisting of a polypeptide that comprises an amino acid sequence as shown in any one of SEQ ID NO.: 48-63 classified in class 530, subclass 387.7.

XIII. Claims 47-51 are drawn to a polynucleotide selected from the group consisting of SEQ ID NO: 20-35 classified in class 536, subclass 23.1.

XIV. Claims 52-59 are drawn to a method of producing in a eukaryotic cell at least one protein comprising at least one unnatural amino acid, classified in class 435, subclass 183.

This application contains claims directed to the following patentably distinct species: Unnatural amino acid from the group selected from an alkynyl or azido moiety, a post translational modification selected from the group of molecules in claim 2 as relevant to groups I and XIV. In addition polypeptides from the group selected from the group SEQ ID NO: 48-63 from group XI or XII.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If applicants elect the inventions in group I or XIV applicants must also elect the unnatural amino acid from the group selected from an alkynyl or azido moiety and the post translational modification selected from the group of molecules in claim 2. In addition if applicants elect the invention of group XI or XII they must also elect a single species of polypeptide from the group selected from the group SEQ ID NO: 48-63. Furthermore if applicants elect the invention in group XIII, they must elect one species from the group selected from SEQ ID NO: 20-35.

The species in the group I and XIV are related because they are all proteins comprising at least one unnatural amino acid with a specific post translational modification. In addition the inventions in group XI and XII are related because they are all RS polypeptides or antibodies specific to the same. The related inventions are distinct if the inventions as claimed do not

overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the different inventions comprise polypeptides with one or more unnatural amino acids with a specific unnatural amino acids and specific post translational modification (I and XIV) or structurally different polypeptides (XI) or different antibodies (XII) or different polynucleotides (XIII). Therefore, where structural identity is required, or expression using said polynucleotides or production of antibodies using polypeptides, the different sequences have different effects.

In addition each of the of the inventions requires a separate patent and non-patent literature search requiring a different text search for each group and thus co examination of the inventions in group I and XIV or XI or different antibodies XII or different polynucleotides XIII would be a serious burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all the claims are generic.

Inventions I, II, III, IV and V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise different compositions/products. Invention I is a polypeptide comprising any unnatural amino acid and invention II and III comprise an unnatural amino acid and an orthogonal tRNA and a cell comprising an unnatural amino acid, Invention IV comprises is an azido dye composition and invention V comprises an alkynyl polyethylene glycol composition therefor each group comprises chemically different products.

Inventions I and II are unrelated to inventions VI-IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions I and II comprise products/compositions not made by the method of inventions VI-IX.

Inventions III are unrelated to inventions VI-IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the cell comprising an unnatural amino acid is not capable of being used in the methods of inventions VI-IX.

Inventions II-V and invention of XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions in inventions II-V can be used in an in-vitro setting. In addition other unnatural amino acids and reactive groups can be used in the method of group XIV.

Inventions IV and VI, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of IV comprise a composition that is not made by the method of invention VI or IX.

Inventions V and VI, VII, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the composition comprising an alkynyl polyethylene glycol of V, and the methods for synthesizing a p-(propargyloxy)phenylalanine compound of invention VI, or the method for synthesizing an azido dye of invention VII and VIII have different mode of operation have different functions or different effects.

Inventions in groups VI, VII, VIII, IX and invention of group XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the various groups of inventions cannot be used together and have different modes of operations, function and effect. In addition the search and examination of each method in invention VI, VII, VIII, IX and XIV in one patent application would result in undue burden, since the searches for all the groups are not co-extensive, since the searches are in different classifications, and involve different field of search. Each of the of the inventions requires a separate patent and non-patent literature search requiring a different text search for each group and thus co examination of the inventions of VI, VII, VIII, IX and XIV would be a serious burden on the examiner.

Invention in group X is unrelated to the compositions or cell of invention I-V and to the methods of synthesis of inventions VI-IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention X is drawn to eukaryotic cells comprising orthogonal tRNA synthetases and invention I-V are drawn to compositions or cell and inventions VI-IX are drawn to methods of synthesizing various compounds.The method of producing an unnatural amino acid compound of group VI-IX is

unrelated to the method of producing a protein comprising an unnatural amino acid of groups I-V or the eukaryotic cell comprising an ORS/OtRNA of group X because these products are structurally and functionally unrelated.

Invention in group II-IX are unrelated to the invention in group XI, XII and XIII drawn to an orthogonal RS (ORS), to antibody specific to the ORS and polynucleotide encoding the ORS. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise a chemically unrelated structure capable of separate manufacture, use and effect.

Invention in group VIII and IX are unrelated to the invention in group XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions in group VIII and IX are drawn to methods of synthesizing chemically unrelated compounds unrelated having different mode of operation, different function capable of separate manufacture, use and effect.

The cell of invention XI is related to the invention of XII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of invention XI can potentially be used as a therapeutic agent.

Inventions XI, XII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise a chemically unrelated structure capable of separate

manufacture, use and effect. The DNA sequences of invention XIII comprises nucleotide sequence and the protein of group XI and the antibody of inventions XII each of which comprise unrelated sequences.

Inventions I and XIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide with an unnatural amino acid can be chemically synthesized.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43).

Applicant is reminded that upon the cancellation of claims to a none elected invention the none elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection

or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kagnew Gebreyesus PhD.

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KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER